DRUGS CONTROL ADMINISTRATION
Government of Telangana

L. Dis. No.4449/E1/2018

Dated: 6-12-2018

To

M/s.Sanmed Healthcare Pvt Ltd
Plot No.56, Biotech Park, Phase-III
Karakapatla(Village), Markook(Mandal)
Siddipet District, Telangana-502279, India

Sir,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of World Health Organisation G.M.P. Certificate – Regarding.

Ref: 1. Your letter dated: 20.06.2018
2. Joint Inspection report dt:24.09.2018 & 25.09.2018.

-x-x-x-x-

With reference to your application cited, I forward herewith **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration, Telangana State and CDSCO, Zonal Office, Hyderabad vide reference 2nd cited.

This Certificate is valid for a period of Three years from the date of issue.

Yours faithfully,

6/12/2018

M.L.V.P.Surendarnath Sai
Joint Director & Licensing Authority(FAC)

DRUGS CONTROL ADMINISTRATION HYDERABAD GOVERNMENT OF TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No.4449/E1/2018 Dated: -12-2018.

LIST OF PRODUCTS APPROVED UNDER WHO-GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

1. Povidone Iodine Solution 10% w/v(Sanmedin 10%)

Composition :

Povidone Iodine USP	- 10% w/v
(Available iodine - 1%)	
Purified Water USP	- Q.S

2. Povidone Iodine Solution 7.5% w/v(Xepi Scrub PVP)

Composition :

Povidone Iodine USP	- 7.5% w/v
(eq. to Available iodine - 0.75%)	
Non Ionic Surfactant	- Q.S
Purified Water USP	- Q.S

3. Solution of 2-Propanol USP, 1-Propanol and Mecetronium Ethylsulphate (Xepi RUB M)

Composition :

2-Propanol IP	- 45% w/w
1-Propanol	- 30% w/w
Mecetronium ethylsulphate	- 0.2% w/w
Colour Brilliant Blue (f.c.f)	- Q.S
Purified Water IP	– Q.S
Skin Protecting Substance.	

Manufacturer : M/s.Sanmed Healthcare Pvt Ltd
Plot No.56, Biotech Park, Phase-III
Karakapatla(Village), Markook(Mandal)
Siddipet District, Telangana-502279, India.

When applicable detailed : Placing the product on the market as above.

It is certified that the above products had been authorized to be placed on the market for use in the Country and exporting countries.

Drug Licence No. : 5/MD/TS/2015/F/G, dated:04.08.2015 under Form – 25 valid upto 31.12.2020.

It is also certified that (a) the manufacturing plant in which the product is produced is subject to inspection at suitable intervals.

DRUGS CONTROL ADMINISTRATION ★ HYDERABAD ★ GOVERNMENT OF TELANGANA

6/12/2018

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No.4449/E1/2018

Dated: 6-12-2018.

Issue of WHO GMP CERTIFICATE TO M/s.Sanmed Healthcare Pvt Ltd, Plot No.56, Biotech Park, Phase-III, Karakapatla(Village), Markook(Mandal), Siddipet District, Telangana-502279, India

The Unit M/s.Sanmed Healthcare Pvt Ltd, Plot No.56, Biotech Park, Phase-III, Karakapatla(Village), Markook(Mandal), Siddipet District, Telangana-502279, India was inspected jointly by Mr.G.Narendra Kumar, Drugs Inspector, CDSCO, Hyderabad and Mr.T.Raja Mouli, Drugs Inspector, Sangareddy (Mfg) Drugs Control Administration, Hyderabad on 24.09.2018 & 25.09.2018.

(b) The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacturer and Quality Control (As recommended by the World Health Organisation) in respect of 03 (Three) products to be sold or distributed with in the Country or origin (or to be exported).

This Certificate is valid for Three years from the date of issue.

6/12/2018

M.L.V.P.Surendarnath Sai
Joint Director & Licensing Authority(FAC)

DRUGS CONTROL ADMINISTRATION HYDERABAD GOVERNMENT OF TELANGANA